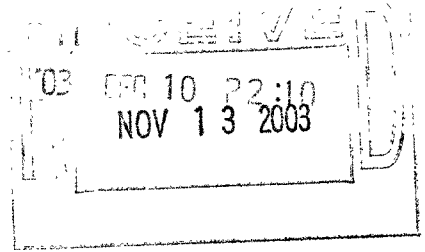


EMORD & ASSOCIATES, P.C.

BURKE PROFESSIONAL CENTER
5282 LYNHATE COURT
BURKE, VIRGINIA 22015

1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036

PHONE: (202) 466-6937 • FAX: (202) 466-6938
WEB SITE: www.emord.com
E-MAIL: kbalmford@emord.com



November 7, 2003

VIA UPS NEXT DAY AIR

Dr. Robert Moore
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

***Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93***

Dear Dr. Moore:

Pure Encapsulations, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Pure Encapsulations, Inc. retains scientific documentation supporting the statements.

1. Supplement Brand Name

Astaxanthin

Ingredients

Astaxanthin (naturally derived from *Haematococcus pluvisilis* microalgae), lutein (naturally occurring), vitamin A (as beta carotene) (naturally occurring), vitamin E (d-alpha tocopherol), rosemary liquid extract, high oleic safflower oil, and gelatin.

Text of Statements of Nutritional Support

Powerful antioxidant for the skin, macula, joints, immune system and cardiovascular function.

¹ The address for Pure Encapsulations, Inc. is 490 Boston Post Road, Sudbury, MA 01776.

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Derived from Hawaiian Haematococcus pluvialis microalgae cultivated under pristine conditions, esterified astaxanthin is a stable, powerful, fat-soluble antioxidant from the carotenoid family.

Astaxanthin is different from beta-carotene in that it has two additional oxygenated groups on each of its ring structures, enhancing its ability to scavenge free radicals.

It is believed to be several hundred times more effective than vitamin E in neutralizing singlet oxygen molecules and has been shown to exert greater antioxidant activity than both zeaxanthin and lutein.

Astaxanthin protects the phospholipids membranes of cells from oxidative damage.

In a recent U.S. study, it demonstrated the ability to cross the blood brain barrier and protect the retina in animals, suggesting its potential for supporting the brain and nervous system from free radical damage.

Initial trials with astaxanthin suggest that it may boost the skin's natural antioxidant defenses against ultraviolet-induced free radicals.

In a human clinical evaluation, supplementation with BioAstin astaxanthin for two weeks provided significant antioxidant protection for the skin.

In cell cultures, astaxanthin provided greater protection than both beta-carotene and lutein, in part by supporting catalase and superoxide dismutase activity.

In one double-blind placebo controlled trial, BioAstin astaxanthin significantly supported joint comfort in human volunteers.

The results of another human clinical trial suggest that BioAstin astxanthin supported knee comfort and joint function after strenuous leg exercises.

Subjects in a third study using BioAstin astaxanthin reported enhanced wrist nerve comfort.

Furthermore, a double-blind study conducted in Sweden for the duration of six months revealed physiological benefits for strength and exercise in participants.

Enhanced dietary concentrations of astaxanthin have demonstrated the ability to support healthy immunoglobulin activity and immune function.

Additional studies suggest astaxanthin's immune and cellular support potential.

Astaxanthin provides superior antioxidant power, boosting the natural antioxidant defenses of the skin, supporting macular health, promoting healthy immune and cellular function, enhancing joint and wrist nerve comfort, providing potential support for the digestive environment, and demonstrating lipid and cardiovascular health properties.

2. Supplement Brand Name

OptiBerry™

Ingredients

Proprietary blend of wild blueberry extract, strawberry powder, cranberry powder, wild bilberry extract, elderberry extract and raspberry powder (providing the anthocyanine malvidin, cyaniding, delphinidin, and petunidin in biologically active rations), vitamin C (as ascorbyl palmitate)

Text of Statements of Nutritional Support

Anthocyanins are the primary components that give many fruits and vegetables their rich pigment, as well as provide them with antioxidant protection.

Multiple studies have demonstrated the antioxidant ability of berry extracts to promote healthy skin, cognitive and neuronal function, cardiovascular health and cellular function.

Research performed at the Ohio State University Medical Center reported that OptiBerry helped to support healthy skin by maintaining healthy immune mediator activity in human keratinocytes.

Another study performed at the same center suggested that OptiBerry enhanced cellular and vascular support.

One clinical trial involving elderly women reported that consumption of strawberries , containing a high level of antioxidant phenolic compounds, helped support healthy serum antioxidant capacity.

An animal study demonstrated through a series of tests that the high antioxidant activity of berry extracts, such as strawberry and blueberry, may defend against age-related neuronal and cognitive decline.

Researchers also reported that elderberry anthocyanins were incorporated into the cellular membrane and cytosol of endothelial cells and provided protection against oxidative stress.

Through the use of an accelerated neuronal aging model, another study showed that powerful antioxidants such as blueberry and strawberry extracts provide protective support for central nervous system (CNS) function.

Research has also reported that anthocyanins support healthy cardiovascular function.

OptiBerry provides enhanced antioxidant protection with a bioactive ration of powerful anthocyanins that help to support healthy cardiovascular, skin, cellular and cognitive function.

3. **Supplement Brand Name**

Ashwagandha

Ingredients

Ashwagandha (*Withania somnifera*) (root), hypo-allergenic plant fiber added to complete capsule volume requirement

Text of Statements of Nutritional Support

Helps to counteract the effects of occasional stress, may support cardiovascular, immune, cognitive and joint function.

Ashwagandha is believed to increase energy and overall health and longevity.

Withanolides are key constituents of this herb and play an important role in ashwagandha's overall ability to promote physical and mental health.

A small human clinical trial demonstrated the ability of ashwagandha to support healthy glucose and lipid metabolism.

In a double-blind, placebo-controlled clinical trial involving 42 volunteers, a formulation including ashwagandha indicated its potential to help promote joint comfort, which may involve modulation of cyclooxygenase enzyme activity.

Traditional uses for ashwagandha included support for healthy male sexual function.

Ashwagandha's adaptogenic properties provide multi-functional support for promoting general mental and physical wellness, including support for occasional stress, joints, memory, immune function, and healthy lipid and glucose metabolism.

4. **Supplement Brand Name**

Glucosamine HCl

Ingredients

Glucosamine (shellfish-free) (from 904 mg glucosamine HCl)

Text of Statements of Nutritional Support

Joint support.

In studies, glucosamine HCl has demonstrated the ability to support healthy cartilage integrity, in part by maintaining healthy matrix metalloproteinase (MMP) enzyme activity.

In other studies, formulations containing glucosamine HCl have demonstrated positive effects on joint mobility and comfort.

Pure Encapsulations Glucosamine HCl is a shellfish-free glucosamine source for healthy joint function.

5. Supplement Brand Name

Calcium with Vitamin D₃

Ingredients

Calcium (citrate/malate), vitamin D₃, and vitamin C (ascorbyl palmitate)

Text of Statements of Nutritional Support

Several clinical trials reveal the positive effects of combined supplemental calcium and vitamin D for bone health.

Vitamin D is important for its ability to promote intestinal calcium and phosphorus absorption, reduce urinary calcium loss and enhance healthy bone composition.

In a large trial published in the New England Journal of Medicine involving over 3,000 women, supplementation with calcium and vitamin D daily for one and a half years supported bone composition of the femur.

In another study, calcium and vitamin D supplementation promoted calcium utilization and maintained healthy bones in postmenopausal women.

Calcium citrate malate combined with vitamin D maintained healthy bones in a separate group of postmenopausal women, specifically supporting the spine.

An analysis of several trials indicates a positive influence of calcium on cardiovascular health, and effect that may be most specific for salt-sensitive individuals.

Vitamin D may also provide cardiovascular support for some individuals, which may be attributed to its effect on calcium metabolism or possibly by helping to maintain healthy plasma rennin function.

Additionally, calcium has been associated with supporting distal colon health.

A role for vitamin D in supporting colon health by promoting healthy cellular function has also been suggested.

Preliminary evidence suggests that vitamin D may also support healthy glucose metabolism, since vitamin D receptors are present on the islet cells of the pancreas.

Calcium with Vitamin D₃ supports optimal calcium absorption and bone mineral composition, in addition to promoting potential cardiovascular and colon health.

6. **Brand Name**

Vitamin D₃

Ingredients

Vitamin D₃, hypo-allergenic plant fiber added to complete capsule volume requirement

Text of Statements of Nutritional Support

Supports calcium absorption and bone health, provides potential support for cardiovascular and colon health.

Vitamin D promotes intestinal calcium and phosphorous absorption and reduces urinary calcium loss, essential mechanisms for maintaining proper calcium levels in the body and for healthy bone composition.

Clinical studies involving vitamin D supplementation suggest the importance of vitamin D in addition to calcium for bone health.

Vitamin D supplementation alone may also support bone health.

Vitamin D may also provide cardiovascular support for some individuals, which may be attributed to its effect on calcium metabolism or possibly by helping to maintain healthy plasma rennin function.

A role for vitamin D in supporting colon health by promoting healthy cellular function has also been suggested.

Preliminary evidence suggests that vitamin D may also support healthy glucose metabolism, since vitamin D receptors are present on the islet cells of the pancreas.

Vitamin D₃ enhances calcium absorption and retention, a key nutritional role in supporting healthy bones, and may play a potential role in cardiovascular and colon health.

7. **Brand Name**

Phase 2 Starch Neutralizer®

Ingredients

Phaseolus vulgaris (dried bean fraction), vitamin C (as ascorbyl palmitate), hypo-allergenic plant fiber added to complete capsule volume requirement

Text of Statements of Nutritional Support

Moderates carbohydrate digestion, may support weight loss when combined with a healthy diet and exercise.

Several studies have indicated that partially purified kidney bean extract may help mediate the intraduodenal activity of pancreatic alpha-amylase, thereby moderating carbohydrate digestion.

Alpha-amylase is a key enzyme that catalyzes the hydrolysis of 1,4-alpha-glycosidic linkages in starch, glycogen, and related polysaccharides.

This enzyme is released from both the salivary glands and the pancreas and is involved in the digestion of carbohydrates.

A recent pilot study performed at Georgetown University suggests that kidney bean extract moderates starch digestion and maintains healthy postprandial glucose metabolism in animals.

Additionally, several human studies performed by the Mayo Clinic also report that partially purified kidney bean extract safely modulates starch digestion, supports healthy postprandial glucose metabolism and delays gastric emptying.

These actions helped to maintain healthy starch metabolism, glucose function and satiety in subjects.

Two recent double-blind, placebo controlled, crossover trials reported that Phase 2 moderated carbohydrate digestion by an average of 66% for individuals consuming a high carbohydrate, high fat breakfast.

When taken with a mixed full meal (carbohydrate, protein and fat), Phase 2 demonstrated the potential to moderate carbohydrate digestion by 28%.

Results of one trial indicate that a formulation including Phase 2 helped support healthy weight loss and demonstrated the potential to support healthy triglyceride levels in a study that included 27 participants.

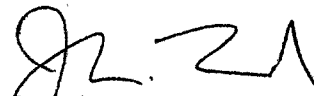
Importantly, purified kidney bean extract maintains activity when exposed to gastric and duodenal juices.

Phase 2 Starch Neutralizer® is distinguished as a standardized, purified extract of Phaseolus vulgaris to be taken before a starch-containing meal or snack, mediating carbohydrate digestion, supporting postprandial glucose metabolism, and providing support for potential weight loss when combined with a healthy diet and exercise.

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another

asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. W. Emord', written over the printed name.

Jonathan W. Emord
Claudia A. Lewis-Eng
Kathryn E. Balmford

Certification

I, Ray Hamel, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on:

11/7/03Ray Hamel